

CLAIMS

Which is claimed is:

1. Methods for estimating the survival rate or mortality rate of patients with a fatal infectious disease following an antibiotic treatment, said methods comprising:
 - (a) determining the survival rate or the mortality rate of controlled patients with the same disease, said controlled patients receiving no treatment, or receiving placebo or an inactive treatment;
 - (b) determining a correlation between (1) the organism eradication rate of said antibiotic and (2) the dose regimen of said antibiotic;
 - (c) estimating the survival rate or the mortality rate of the antibiotic-treated patients based on (1) the survival rate or the mortality rate of the controlled patients, and (2) the organism eradication rate.
2. Methods for providing evidence to support an effective dosing regimen of an antibiotic for treating a fatal infectious disease using the estimated survival rate or mortality rate of said patients, said methods comprising:
 - (a) determining the survival rate or the mortality rate of controlled patients with the same disease, said controlled patients receiving no treatment, or receiving placebo or an inactive treatment;
 - (b) determining a correlation between (1) the organism eradication rate of said antibiotic and (2) the dose regimen of said antibiotic;
 - (c) estimating the survival rate or the mortality rate of the antibiotic-treated patients based on (1) the survival rate or the mortality rate of the controlled patients, and (2) the organism eradication rate;
 - (d) determining the effective dose regimen of said antibiotic by targeting the survival rate or mortality rate of the antibiotic-treated patients.

3. The method of anyone of claims 1 and 2, wherein said correlation between the organism eradication rate and the antibiotic dose regimen is derived utilizing one or more of:
 - (a) the pharmacodynamic marker of said antibiotic;
 - (b) the pharmacokinetics of said antibiotic;
 - (c) the characteristic of said patients.
4. The method of anyone of claims 1 and 2, wherein said disease is Aeromonas bacteraemia, Anthrax, Bacteremia, sepsis , Bacterial meningitis, Candida infections, Community-acquired pneumonia, Epiglottitis, Fournier's gangrene, Infections in bone marrow transplantation, Infections in solid-organ transplantation, Infective endocarditis, Melioidosis, or Spinal infection.
5. The method of anyone of claims 1 and 2, wherein said antibiotic is a aminoglycosides, fluoroquinolones, glycopeptides, β -lactams, macrolides, linezolid, penicillins, cephalosporines, tetracyclines, quinupristin-dalfopristin, or quinolone.
6. The method of anyone of claims 1 and 2, wherein said antibiotic is amifloxacin, amikacin, amoxicillin, ampicillin, azithromycin, carbenicillin, cefaclor, cefadroxil, cefamandole, cefazidime, cefazolin, cefepime, cefmenoxine, cefonicid, cefoperazone, ceforanide, cefotaxime, cefotetan, cefoxitin, cefpodoxime, ceftazidime, ceftizoxime, ceftriaxone, cefuroxime, cephalixin, Cephalothin, chlortetracycline, ciprofloxacin, clarithromycin, clinafloxacin, cloxacillin, demeclocycline, dicloxacillin, dirithromycin, doxycycline, erythromycin, fleroxacin, flurithromycin, gatifloxacin, gemifloxacin, gentamycin, grepafloxacin, josamycin, kanamycin, levofloxacin, lomefloxacin, loracarbef, methacycline, methicillin, mezlocillin, midecamycin, minocycline, miocamycin, moxifloxacin, nafcillin, neomycin, netilmicin, netlimicin, norfloxacin, ofloxacin, oleandomycin, oxacillin, oxytetracycline, pefloxacin, penicillin G, penicillin V, piperacillin,, rokitamycin, rosaramycin, roxithromycin, sparfloxacin, sparfloxacin, spiramycin, streptomycin, teicoplanin, ticarcillin, tobramycin, tobramycin, troleandomycin, trovafloxacin, trovafloxacin, or vancomycin.

7. The method of anyone of claims 1 and 2, wherein said organism eradication rate is the one against the organisms causing the said disease or the one against similar organisms susceptible to said antibiotic.
8. The method of anyone of claims 1 and 2, wherein said organism eradication rate is obtained from human, animal, or in vitro studies.
9. The method of anyone of claims 1 and 2, wherein said organism eradication rate reflects time-dependency of the percentage or the ratio of the patients with a positive culture of the organisms, relative to the total number of patients initially infected with the organisms.
10. The method of anyone of claims 1 and 2, wherein said pharmacodynamic marker is one of or a combination of the following:
 - (a) C_{max}/MIC: The ratio of the maximum plasma drug concentration to the minimum inhibitory concentration;
 - (b) AUC/MIC: The ratio of the area under the plasma drug concentration curve to the minimum inhibitory concentration;
 - (c) T_{mic}: Time for which the plasma drug concentration exceeds MIC;
 - (d) AUC_{>mic}: Area under the drug concentration curve for which the concentration exceed MIC;
 - (e) PK parameters: Pharmacokinetic parameters that are derived from the antibiotic plasma concentration.
11. The method of anyone of claims 1 and 2, wherein said characteristic of said patients is one of or a combination of the following: age, body weight, gender, body surface areas, and creatinine clearance.
12. The method of anyone of claims 1 and 2, wherein said characteristic of said patients is one or a combination of: demographic variables, blood chemistry parameters, physiological biomarkers, or pathological biomarkers.
13. The method of anyone of claims 1 and 2, wherein the estimated survival rate or the estimated mortality rate in antibiotic-treated patients are verified by comparing the

estimation with the observed survival rate or the observed mortality rate in antibiotic-treated patient patients.

14. The method of anyone of claims 1 and 2, wherein said correlation consists of one or more mathematical equations, statistical equations, or empirical expressions.
15. The method of anyone of claims 1 and 2, wherein said effective dose regimen is a dose regimen that results in increases in patient survival rate or decreases in patient mortality rate.

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